



K96233

Landos Inc.

A SUBSIDIARY OF GROUP LANDANGER CAMUS

OCT - 3 1996

3. SUMMARY OF SAFETY AND EFFECTIVENESS

**MANUFACTURER
IDENTIFICATION:**

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SPONSOR IDENTIFICATION

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**ESTABLISHMENT REGISTRATION
NUMBER:**

2530066

OFFICIAL CONTACT PERSON:

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**DATE OF PREPARATION
OF THIS SUMMARY:**

May 22, 1996

TRADE NAME:

TWIST-OFF™ SCREW

COMMON NAME:

Bone Fixation Screw

**CLASSIFICATION NAME
AND REFERENCE:**

Screw, Fixation, Bone
(21 CFR, Section 888.3040)

PROPOSED REGULATORY CLASS:

Class II

000013

DEVICE PRODUCT CODE:	87HWC
PANEL CODE:	87OR
DESCRIPTION OF DEVICE:	The TWIST-OFF™ SCREW is a threaded Titanium bone fixation appliance intended to be implanted. It is composed of a self-tapping, self-compressive screw and support as a single piece. These two components separate when the screw head comes in contact with the cortex. Screws come in lengths of 11,12,13 and 14 mm; the support does not vary in size.
INTENDED USE:	The TWIST-OFF™ SCREW is intended to be implanted for fixation of bone fractures or bone reconstructions.
INDICATIONS FOR USE:	The TWIST-OFF™ SCREW is indicated for fixing and stabilizing elective osteotomies of metatarsals and phalanges of the foot.
PREDICATE DEVICE:	The TWIST-OFF™ SCREW is substantially equivalent to the M3 Screw system (Osteomed) (K924018, K924138), the Luhr Screw System (Howmedica)(K950595) and the Cortex Screw (Synthes)(K952272).
COMPARISON OF USES/ TECHNOLOGICAL CHARACTERISTICS:	Both the TWIST-OFF™ SCREW and its predicates have the same intended use. All are used for fixation of small bones. The M3 and TWIST-OFF™ SCREW are made of the same Titanium alloy. The Cortex is made from a different Ti alloy; the Luhr Screw is made from Cobalt-Chromium. The M3 and the TWIST-OFF™ SCREW are partially threaded and are self-tapping low profile head screws. Both the M3 and the TWIST-OFF™ SCREW can be used with a power drill.
SUMMARY OF STUDIES:	Rupture torque of the TWIST-OFF™ SCREW was compared with requirements of the French Standard N° NF-F-90-414 and found to have a resistance to torsion in compliance with the selected Standard.

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